

REMARKS

By this paper, claim 14 has been canceled. Claims 1-7, 9, 15,16, 18-21 and 24 are pending.

It is to be noted that on June 24, 2008, the Examiner authorized the conversion of the pending claims to method claims. Despite being recast as a method, the claims now stand as finally rejected in view of newly cited art in a first Office action subsequent to the conversion.

In the final Office action dated July 9, 2008, claim 21 was withdrawn from consideration as being drawn to a non-elected invention/species. Additionally, claims 1-3, 7, 9, 14, 15 and 24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Walker (4,637,382) in view of Taylor (3,902,482). Moreover, claims 4-6 were rejected under § 103(a) as being unpatentable over Walker in view of Taylor and further in view of Martinelli et al. (6,409,729) and claim 16 was rejected under § 103(a) as being unpatentable over Walker in view of Taylor and further in view of Fischer et al. (5,352,190).

It is respectfully submitted, however, that the pending claims recite subject matter which is non-obvious in view of the cited art. Further, it is submitted that there is an insufficient basis for combining the teachings of the cited art and that improper hindsight was used in order to make such combination of teachings.

Significantly, MPEP 2143.01 provides that “a statement that modifications of the prior art to meet the claimed invention would have been ‘well within the ordinary skill in the art at the time the claimed invention was made’ because references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references” and “rejections on obviousness can not be sustained as mere conclusionary statements; instead,

there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” Furthermore, the MPEP states “if the proposed modification or combination of the prior art would change the principal of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.”

Recent case law supports the above. In Innogenetics v. Abbott Labs, 512 Fed. 3d 1363 (Fed. Cir. 2008), the Federal Circuit stated “you must still be careful not to allow hindsight reconstruction of references to reach the claimed invention without any explanation as to how or why the references would be combined to produce the claimed invention.” Moreover, in affirming a non-obvious conclusion, the Federal Circuit in Takeda Chem. Indus. v. Alphapharm Pty. LTD., 492 F 3d 1350 (Fed. Cir. 2007), cited its own precedent that some motivation for modifying the prior art must still be found to conclude that the subject matter was obvious. Moreover, the Board of Patent Appeals and Interferences in Ex parte Whalen et al. (Appeal 2007-4423) concluded that with regard to obviousness, it must be shown that those of ordinary skill in the art would have had some apparent reason to modify the teachings of the art in a way to result in the claimed subject matter and that the analysis supporting that reasoning must be made explicit.

In the present situation, the Examiner has stated that Walker discloses a method involving controlling a load on articular cartilage to treat arthritic conditions affecting a joint. The Examiner then stated that Walker discloses the claimed invention except for certain aspects provided by Taylor. Specifically, the Examiner stated that the Walker reference discloses the “claimed invention except for the link assembly including means for limiting the angular displacement of the fixation assemblies relative to the link assembly and including means for

varying separation of the first fixation assembly and the second fixation assembly as a function of an angular displacement of either fixation assembly relative to the link assembly being coupled to the first fixation assembly by a first pivot having one or two degrees of rotation freedom and coupled to the second fixation assembly by a second pivot point and for the link assembly including a fixed separation member from maintaining said first and second pivots and a fixed distance of separation.” In combining the teachings of Walker and Taylor, the Examiner stated “it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Walker with an apparatus including a link assembly including means for limiting angular displacement of the fixation assemblies relative to the link assembly and including means for varying separation of the first fixation assembly and the second fixation assembly as a function of the angular displacement of either fixation assembly relative to the link assembly being coupled to the first fixation assembly by a first pivot having one or two degrees of rotation freedom and coupled to the second fixation assembly by a second pivot, and for the link assembly including a fixed separation member from maintaining said first and second pivots at a fixed distance of separation in view of Taylor to provide a pivotal movement closely simulating the flexing action of an anatomical knee.”

However, it is respectfully submitted that this reasoning is flawed in a number of respects.

As an initial matter, it is respectfully submitted that the Examiner’s reliance upon Walker for the teaching of a method involving controlling a load on articular cartilage to treat arthritic conditions affecting a joint is misplaced. Significantly, Walker simply does not contemplate treating arthritic conditions and consequently does not recognize a need to control loads on articular cartilage to treat arthritis.

Secondly, in rejecting claims 1-3, 7, 9, 14, 15 and 24 under § 103(a), the Examiner relied on the Walker reference as teaching a method including an apparatus having “a link assembly (ref. #22) configured to the span anatomy affected by arthritic conditions but lacking fractures, the first and second fixation of assembly thereby each being angular displaceable relative to the link assembly.” Notably, independent claim 1 as well as each of the other pending claims recite a method involving an apparatus including a link assembly coupled to a first fixation assembly by a first pivot and to a second fixation assembly by a second pivot. However, it is significant that Walker actually discloses a linkage which “consists of an extension 22 of the tibial plate,” one which does not pivot with respect to the tibial plate. Thus, the Walker linkage is not coupled to a first fixation assembly by a pivot and to a second fixation assembly by a pivot as is recited in the claims. Therefore, it is respectfully submitted that the pending claims are not obvious under § 103(a) in view of the cited art.

Thirdly, independent claim 1 as well as the other pending claims each of which depend from claim 1, recite a method involving an apparatus which provides reductions of pressure on at least a portion of a joint without substantially resisting an angular displacement associated with relatively full mobility of the first and second bones of the joint. It is respectfully submitted that neither Walker nor Taylor teach or disclose such subject matter. In fact, the Examiner is silent as to this limitation when applying the Walker and Taylor references. Moreover, Walker cannot be said to teach structure which reduces pressure without substantially resisting an angular displacement associated with relatively full mobility of bones of a joint because even the Examiner has recognized that something is needed to provide the Walker approach with pivotal movement closely simulating the flexing action of an anatomical knee. In that respect, Walker is indeed lacking as it teaches structure which guides motion essentially within two dimensions.

Taylor is also lacking, however, in the teaching of an approach which permits relative full mobility of joint members as its disclosure relates to structure which is based upon movement of pins within well-defined, arcuate slots. Taylor is in fact directed towards a leg brace designed to “protect the knee from severe blows or stress” and specifically states that leg braces require a mechanical joint “which will take some of a medially or laterally applied load off the knee joint.” With reference to FIG. 1, it becomes clear that the brace of Taylor does not carry any load resulting from the natural motion of the leg, but rather attaches external to a person’s leg and to the shoe of a wearer without any engagement with a surface along which the wearer would travel. Further, Taylor acknowledges that the disclosed knee brace restricts movement of a knee joint to provide the required support. Therefore, the combination of Walker with Taylor falls short of the subject matter recited in the claims since their teachings do not result in providing reduction in pressure on at least a position of a joint without substantially reducing angular displacement associated with full mobility of the joint. Thus, it is respectfully submitted that on these bases as well, a *prima facie* case of obviousness has not been presented to reject the claims.

Fourth, it is respectfully submitted that relying on Taylor for the teaching of means for limiting the angular displacement of fixation assemblies relative to a lock assembly is in contradiction to the Examiner’s stated reason for modifying Walker in view of Taylor. That is, means for limiting angular displacement contradicts providing “pivoted movement closely simulating the flexing motion of an anatomical knee.” Adding Taylor to Walker, then, actually functions to move the cited art further away from providing relatively full mobility, which is subject matter recited in each of the pending claims. Thus, it is believed that the combination of Walker and Taylor is also inappropriate for this reason.

Fifth, the Examiner has not made explicit the analysis employed to combine the cited art. The Examiner has merely stated that it would have been obvious to one of ordinary skill in the art to make the various combinations, but the Examiner did not address how or why the cited references might be combined. In fact, combining Walker with Taylor is actually contrary to the teachings of Walker. At Col. 1, ln. 35 et seq., Walker states that external linkages have been found to be unsatisfactory “because they provide only approximate motion and are not compatible with the more exacting motion requirements of the internal structures of the knee.” Since Taylor is directed to an external linkage, it is respectfully submitted that it would not have been obvious to one of ordinary skill in the art to combine Walker with Taylor.

Further, it is respectfully submitted that so thoroughly and significantly modifying Walker in view of Taylor in the manner suggested by the Examiner would change the principle of operation of Walker. Here, the Examiner has used no less than one hundred words to simply list the structures and features of Taylor to be added to Walker. Also, in the event it is the Examiner’s intention that Walker should be modified to include a link assembly coupled to a first fixation assembly by a first pivot and to a second fixation assembly by a second pivot, it is to be recognized that adding this structure would be in direct contradiction with the teachings of Walker. Significantly, Walker states that to provide desired polycentric motion of a circular surface 20 on the planar surface 18, a linkage 22 is configured with a slot 24 which receives a pin 26, the pin and slot arrangement permitting the pin to move in the direction y but not in the direction x. Clearly, adding the link arrangement of Taylor to Walker would undermine this objective. Therefore, it is respectfully submitted that modifying Walker with the teachings of Taylor was accomplished in contradiction of the guidance provided by the MPEP.

This lack of providing the necessary detailed analysis also affects the rejections of the claims depending from independent claim 1. For example, the Applicant cannot see how the cited Walker and Taylor references teach as is recited in dependent claim 3, a clamp for mounting a plurality of pins each for engaging the first bone, said plurality of pins being spaced along the length of the first fixation assembly. Also, it cannot be seen how the subject matter recited in at least claims 7, 9, 15 and 24 can be met by modifying Walker in view of Taylor without also changing the principle operation of the approach suggested by the Walker reference. Thus, it is also respectfully submitted that the subject matter recited in these dependent claims are not obvious.

Much of the same can be said with respect to the combination of Martinelli et al. with the Walker and Taylor references to reject claims 4-6 under § 103(a), as well as adding the teachings of Fischer et al. to the combination of Walker and Taylor to reject claim 16 under § 103(a). There, it was said that one of ordinary skill in the art would have further modified Walker and Taylor with Martinelli et al. “to allow greater freedom of movement” and Fischer et al. was added to the teachings of Walker and Taylor “to strengthen the joint.” Again, these conclusionary statements were made without providing an explicit analysis as to how the combinations of teachings could be accomplished. Also, the stated reason of allowing a greater freedom of movement is again in contradiction with any statement or implication that Walker and Taylor, alone or in combination, provide relatively full mobility. Accordingly, it is submitted that improper hindsight was also used to combine Martinelli and Fischer et al. with Walker and Taylor.

CONCLUSION

Applicant has attempted to completely respond to the outstanding Office action. In view of the above amendments and remarks, Applicant respectfully requests that the application be reconsidered, the claims allowed and the application passed to issue. In the event that the present application cannot for some reason be passed to issue, the Applicant respectfully requests that the finality of the outstanding Office action be withdrawn in view of the foregoing arguments as well as in view of the fact that new art was applied to finally reject the pending method claims in a first Office action subsequent to the conversion of the claims to a method.

Respectfully submitted,

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